

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Pancrex V 125 mg hard capsules

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each hard capsule contains 125 mg pancreatin to provide enzymatic activity per capsule not less than:

Free protease	160 BP units
Lipase	2950 BP units
Amylase	3300 BP units

For the full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Hard capsule (capsule).

A white or buff coloured powder in clear hard gelatin capsules.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Pancrex V is used to compensate for reduced intestinal enzyme activity in pancreatic deficiency states.

It is indicated for the treatment of fibrocystic disease of the pancreas (cystic fibrosis), chronic pancreatitis and pancreatic steatorrhoea following pancreatectomy. It may also be indicated following gastrectomy as an aid to digestion.

#### **4.2 Posology and method of administration**

##### Posology

These low dose capsules may be used when small amounts of Pancrex V are required, for example for neonates.

Dosage should be adjusted according to the needs of the individual patient and the amount of food consumed.

The following dosage scale provides a suitable basis for adjustment.

*Paediatric population*

Neonates: The contents of 1-2 capsules mixed with feeds.

Method of administration

Oral use.

The capsules should be taken with each feed or before a meal.

If the capsule contents are mixed with liquids or feeds the resulting mixture should not be allowed to stand for more than one hour prior to use.

**4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

It is possible that some irritation of the skin of the mouth may occur if capsules are chewed or the contents retained in the mouth. Irritation of the anus may also occur. A barrier cream may prevent this local irritation.

Allergic/asthmatic reactions have occasionally occurred on handling the capsule contents.

**4.5 Interaction with other medicinal products and other forms of interaction**

None known.

**4.6 Fertility, pregnancy and lactation**

Pancrex V should not be used in pregnancy and lactation unless clearly necessary but if required should be used in doses sufficient to provide adequate nutritional status.

**4.7 Effects on ability to drive and use machines**

Pancrex V has no or negligible influence on the ability to drive and use machines.

**4.8 Undesirable effects**

Rare cases of hyperuricosuria and hyperuricaemia have been reported when extremely high doses of pancreatin have been taken.

Strictures of the ileo-caecum and large bowel, and colitis, have been reported in children with cystic fibrosis taking high doses of pancreatic enzyme supplements. To

date Pancrex and Pancrex V presentations have not been implicated in the development of colonic damage. However unusual abdominal symptoms or changes in abdominal symptoms should be reviewed to exclude the possibility of colonic damage especially if the patient is taking in excess of 10,000 units/kg/day of lipase.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellocard](http://www.mhra.gov.uk/yellocard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **4.9 Overdose**

None stated.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Digestives, incl. enzymes, enzyme preparations, ATC code: A09AA02.

#### Mechanism of action

Pancreatin is derived from porcine pancreas and contains the enzymes, amylase, protease and lipase. The enzymes have the same actions as pancreatic juice and when administered to patients with pancreatic insufficiency improve the ability to metabolise starches, proteins and fats.

## **5.2 Pharmacokinetic properties**

Pancreatin hydrolyses fats to glycerol and fatty acids, changes proteins into proteases and derived substances, and converts starch into dextrins and sugars.

## **5.3 Preclinical safety data**

No relevant pre-clinical safety data has been generated.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Capsule shell

Gelatin

Capsule content

Aluminium oxide

Magnesium stearate

Microcrystalline cellulose

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years.

**6.4 Special precautions for storage**

Store in a refrigerator (2°C - 8°C).

**6.5 Nature and contents of container**

The drug product is contained in a polypropylene securitainer with low density polyethylene cap.

Securitainer: 300 and 500 capsules.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

No special requirements.

**7 MARKETING AUTHORISATION HOLDER**

Essential Pharmaceuticals Limited  
8a Crabtree Road, Egham,  
Surrey, TW20 8RN,  
UK.

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 41094/0005

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

Date of first authorisation: 13/11/1985

Date of latest renewal: 04/11/2003

**10     DATE OF REVISION OF THE TEXT**

10/06/2022